DIAMETRICS MEDICAL

NOV 1 5 2001

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA1990 and 21 CFR 807.92.

The assigned 510(k) number is: K011586 .

Submitter:	Diametrics Medical, Inc. 2658 Patton Rd Roseville, MN 55113 Phone: (651) 638-1250 Fax: (651) 638-1060 Contact Person: Nancy Ring
Establishment Registration Number:	2183953
Summary Prepared on:	May 21, 2001
Identification of Device:	
Device Name:	GL Cartridge
Proprietary Name:	IRMA® SL Blood Analysis System GL Cartridge
Common Name:	Glucose Test System
Classification Name:	Glucose
Device Classification:	Class II
Regulation Number:	21 CFR 862.1345
Panel:	Chemistry (75)
Product Code:	CGA
Name of Predicate Device:	YSI Model 2300 Stat Plus.
Predicate Device 510(k) Number:	K891480
Predicate Device Product Code:	75 CGA

Substantial Equivalence Claim

The IRMA® SL Blood Analysis System GL Cartridge is substantially equivalent in method, intended use and clinical performance to the currently marketed YSI Model 2300 Stat Plus.

Device Description

The IRMA® SL Blood Analysis System GL Cartridge is for use with the IRMA®Blood Analysis System. The GL cartridge is a single use, disposable cartridge, for the in vitro measurement of analytes in whole blood. The GL cartridge comprises the analytes sodium, potassium (K945240), chloride (K981270) and glucose. Diametrics currently markets cartridges with sodium, potassium, (K945240) and chloride.

Samples are introduced via syringe or capillary injections with the IRMA® Capillary Collection Device. The glucose sensor uses an amperometric electrode along with a reference electrode that measures the glucose oxidase reaction. The IRMA® sensors are calibrated prior to each test using a calibrant packaged with the sensors. Calibration of the cartridge is completed when information determined at the factory for each lot of cartridges is combined with measurements taken during the calibration process. Factory derived calibration parameters are input into the analyzer by calibration code entry.

Throughout the calibration and analysis process, signals from the sensors are analyzed. If any abnormal conditions are detected, an error message is generated and the test will be terminated. If there are no abnormal conditions, then the sample results (measured and calculated) are displayed after successful calibration and analysis. In addition, the user has the option to print a hard copy of the results.

Intended Use

The GL Cartridge is intended for professional use with the IRMA® Blood Analysis System for the direct measurement of glucose, sodium, potassium, and chloride in human whole blood. The GL Cartridge and the IRMA® Blood Analysis System are for in vitro diagnostic use.

Indications for Use

The electrolyte measurements (Na^+, K^+, Cl^-) are used to assess hydrational status, aid in the diagnosis of respiratory and metabolic acid-balance, and prevention of cardiac arrhythmia. Common disease states, which use these measurements for diagnosis, are acid-base disturbances, dehydration, diarrhea, ketoacidosis, alcoholism and other toxicities.

The measurement of glucose aids in the diagnosis and treatment of diabetes mellitus, neonatal hypoglycemia and idiopathic hypoglycemia.

Summary of Technological Characteristics
The following table shows comparison to the predicate device.

	IRMA®	YSI Model 2300 Stat Plus
Detection Method	Glucose Oxidase	Glucose Oxidase
Analytes measured	Na^+, K^+,Cl-, and glucose	Glucose, Lactate
Measuring Range	Glucose: 20 - 500 mg/dL	Glucose: 0-500 mg/dL in Normal mode 0-900 mg/dl in Screening Mode
Operating Temp.	15-30°C (59-86°F)	15.0-35°C (59-95°F)
Operating Humidity	0-80%	10-90%* *Non-condensing
Sample	Whole blood 0.2 - 3.0 mL, from syringe 0.125 mL from capillary collection device	Glucose: Whole Blood, serum, or plasma 25 µL aspirated volume
Power	7.2 V NiCAD rechargeable battery or AC adapter	120 VAC 240 VAC
Reagents	Supplied in self-contained disposable cartridge	Supplied in a Buffer Concentrate (YSI 2357) that is added to water and a liquid Calibrator solution (YSI 2747)
Weight	5 lbs.	25 lbs.
Results	Display and printer on board	Display and printer on board
Calibration	Automatic with each sample	Self calibrates every 5 samples or 15 minutes, or after a calibration shift of 2% or greater, or after a sample chamber temperature drift of more than 1° C.
Sensors	Disposable single-use	Reusable sensor probes

Summary of Performance Data:

Accuracy:

Analyte	n	Range evaluated	Slope	Intercept	r	Sy.x
Glucose	37	19 - 338 mg/dl	0.97	5.47	0.992	11.08

Precision

Level	N	IRMA Glucose Mean (mg/dl)	IRMA Glucose Total Precision sd	IRMA Glucose Total Precision %CV
1	59	47.7	2.9	5.9
2	58	103.0	4.6	4.5
3	60	198.5	7.8	4.0
4	59	351.3	16.8	4.8

Linearity:

Analyte	n	Measured Range	Assessment
Glucose	20	20-500 mg/dl	Linear

Conclusions:

The data demonstrates that the GL Cartridge is as safe, effective and performs as well as the legally marketed predicate device to which equivalence is claimed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 16 2001

Ms. Nancy Ring
Regulatory Affairs and Clinical Support Specialist
Diametrics Medical, Inc.
2658 Patton Road
Roseville, MN 55113

Re: K011586
Trade/Device Name: IRMA® SL Blood Analysis System GL Cartridge
Regulation Number: 21 CFR 862.1345, 862.1170, 862.1600, 862.1665
Regulation Name: Glucose Test System, Chloride Test System, Potassium Test System, Sodium Test System
Regulatory Class: II
Product Code: CGA, CGZ, CEM, JGS
Dated: August 23, 2001
Received: August 24, 2001

Dear Ms. Ring:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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K011586

Statement of Indications For Use

Intended Use

The glucose sensor is intended for professional use with the IRMA® Blood Analysis System for the direct measurement of glucose, in human whole blood. The GL Cartridge and the IRMA® Blood Analysis System are for in vitro diagnostic use.

Indications for Use

The measurement of glucose aids in the diagnosis and treatment of diabetes mellitus, neonatal hypoglycemia and idiopathic hypoglycemia.

Alan Coopy

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 011586

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109) (Optional Format 1-2-96)